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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/993,211	11/16/2001	Beryl Asp	01-1720	8080

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Lisa M.W. Hillman
McDonnell Boehnen Hulbert & Berghoff
32nd Floor
300 S. Wacker Drive
Chicago, IL 60606

EXAMINER	
UNGAR, SUSAN NMN	
ART UNIT	**PAPER NUMBER**
1642	

DATE MAILED: 02/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/993,211	ASP ET AL.	
	Examiner	Art Unit	
	Susan Ungar	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *16 November 2001*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) *1-22* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. Claims 1-22 are pending in the application and are currently under prosecution.

2. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

3. Claim 1 links inventions 1-9. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim 1. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Group 1. Claims 1, 4-6, 13 are drawn to a method of treating breast cancer which overexpresses HER2 which comprises administering trastuzumab in combination with dexrazoxane effective to ameliorate cardiotoxicity, classified in Class 424, subclass 130.1 .

Group 2. Claims 1, 4-5, 13 are drawn to a method of treating uterine endometrium cancer which overexpresses HER2 which comprises administering

trastuzumab in combination with dexrazoxane effective to ameliorate cardiotoxicity, classified in Class 424, subclass 130.1 .

Group 3. Claims 1, 4-5, 13 are drawn to a method of treating pancreas cancer which overexpresses HER2 which comprises administering trastuzumab in combination with dexrazoxane effective to ameliorate cardiotoxicity, classified in Class 424, subclass 130.1 .

Group 4. Claims 1, 4-5, 13 are drawn to a method of treating colon cancer which overexpresses HER2 which comprises administering trastuzumab in combination with dexrazoxane effective to ameliorate cardiotoxicity, classified in Class 424, subclass 130.1 .

Group 5. Claims 1, 4-5, 13 are drawn to a method of treating ovaries cancer which overexpresses HER2 which comprises administering trastuzumab in combination with dexrazoxane effective to ameliorate cardiotoxicity, classified in Class 424, subclass 130.1 .

Group 6. Claims 1, 4-5, 13 are drawn to a method of treating lung cancer which overexpresses HER2 which comprises administering trastuzumab in combination with dexrazoxane effective to ameliorate cardiotoxicity, classified in Class 424, subclass 130.1 .

Group 7. Claims 1, 4-5, 13 are drawn to a method of treating stomach cancer which overexpresses HER2 which comprises administering trastuzumab in combination with dexrazoxane effective to ameliorate cardiotoxicity, classified in Class 424, subclass 130.1 .

Group 8. Claims 1, 4-5, 13 are drawn to a method of treating salivary gland cancer which overexpresses HER2 which comprises administering trastuzumab in combination with dexrazoxane effective to ameliorate cardiotoxicity, classified in Class 424, subclass 130.1 .

Group 9. Claims 1, 4-5, 13 are drawn to a method of treating head and neck cancer which overexpresses HER2 which comprises administering trastuzumab in combination with dexrazoxane effective to ameliorate cardiotoxicity, classified in Class 424, subclass 130.1 .

4. Claim 2 links inventions 9-18. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim 2. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Group 10. Claims 2, 7-9, 14 are drawn to a method of treating breast cancer which overexpresses HER2 which comprises administering trastuzumab

in association with an anthracycline, in combination with dexrazoxane effective to ameliorate cardiotoxicity, classified in Class 424, subclass 130.1 .

Group 11. Claims 2, 7-8, 14 are drawn to a method of treating uterine endometrium cancer which overexpresses HER2 which comprises administering trastuzumab in association with an anthracycline, in combination with dexrazoxane effective to ameliorate cardiotoxicity, classified in Class 424, subclass 130.1 .

Group 12. Claims 2, 7-8, 14 are drawn to a method of treating pancreas cancer which overexpresses HER2 which comprises administering trastuzumab in association with an anthracycline, in combination with dexrazoxane effective to ameliorate cardiotoxicity, classified in Class 424, subclass 130.1 .

Group 13. Claims 2, 7-8, 14 are drawn to a method of treating colon cancer which overexpresses HER2 which comprises administering trastuzumab in association with an anthracycline, in combination with dexrazoxane effective cardiotoxicity, classified in Class 424, subclass 130.1 .

Group 14. Claims 2, 7-8, 14 are drawn to a method of treating ovaries cancer which overexpresses HER2 which comprises administering trastuzumab in association with an anthracycline, in combination with dexrazoxane effective to ameliorate cardiotoxicity, classified in Class 424, subclass 130.1 .

Group 15. Claims 2, 7-8, 14 are drawn to a method of treating lung cancer which overexpresses HER2 which comprises administering trastuzumab in association with an anthracycline, in combination with dexrazoxane effective to ameliorate cardiotoxicity, classified in Class 424, subclass 130.1 .

Group 16. Claims 2, 7-8, 14 are drawn to a method of treating stomach cancer which overexpresses HER2 which comprises administering trastuzumab in association with an anthracycline, in combination with dexrazoxane effective to ameliorate cardiotoxicity, classified in Class 424, subclass 130.1 .

Group 17. Claims 2, 7-8, 14 are drawn to a method of treating salivary gland cancer which overexpresses HER2 which comprises administering trastuzumab in association with an anthracycline, in combination with dexrazoxane effective to ameliorate cardiotoxicity, classified in Class 424, subclass 130.1 .

Group 18. Claims 2, 7-8, 14 are drawn to a method of treating head and neck cancer which overexpresses HER2 which comprises administering trastuzumab in association with an anthracycline, in combination with dexrazoxane effective to ameliorate cardiotoxicity, classified in Class 424, subclass 130.1 .

5. Claim 3 links inventions 19-27. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim 2. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double

patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Group 19. Claims 3, 10-12, 15 are drawn to a method of treating breast cancer which overexpresses HER2 which comprises administering trastuzumab in association with epirubicin, in combination with dexrazoxane effective to ameliorate cardiotoxicity, classified in Class 424, subclass 130.1 .

Group 20. Claims 3, 10-11, 15 are drawn to a method of treating uterine endometrium cancer which overexpresses HER2 which comprises administering trastuzumab in association with epirubicin, in combination with dexrazoxane effective to ameliorate cardiotoxicity, classified in Class 424, subclass 130.1 .

Group 21. Claims 3, 10-11, 15 are drawn to a method of treating pancreas cancer which overexpresses HER2 which comprises administering trastuzumab in association with epirubicin, in combination with dexrazoxane effective to ameliorate cardiotoxicity, classified in Class 424, subclass 130.1 .

Group 22. Claims 3, 10-11, 15 are drawn to a method of treating colon cancer which overexpresses HER2 which comprises administering trastuzumab in association with epirubicin, in combination with dexrazoxane effective cardiotoxicity, classified in Class 424, subclass 130.1 .

Group 23. Claims 3, 10-11, 15 are drawn to a method of treating ovaries cancer which overexpresses HER2 which comprises administering trastuzumab

in association with epirubicin, in combination with dexrazoxane effective to ameliorate cardiotoxicity, classified in Class 424, subclass 130.1 .

Group 24. Claims 3, 10-11, 15 are drawn to a method of treating lung cancer which overexpresses HER2 which comprises administering trastuzumab in association with epirubicin, in combination with dexrazoxane effective to ameliorate cardiotoxicity, classified in Class 424, subclass 130.1 .

Group 25. Claims 3, 10-11, 15 are drawn to a method of treating stomach cancer which overexpresses HER2 which comprises administering trastuzumab in association with epirubicin, in combination with dexrazoxane effective to ameliorate cardiotoxicity, classified in Class 424, subclass 130.1 .

Group 26. Claims 3, 10-11, 15 are drawn to a method of treating salivary gland cancer which overexpresses HER2 which comprises administering trastuzumab in association with epirubicin, in combination with dexrazoxane effective to ameliorate cardiotoxicity, classified in Class 424, subclass 130.1 .

Group 27. Claims 3, 10-11, 15 are drawn to a method of treating head and neck cancer which overexpresses HER2 which comprises administering trastuzumab in association with epirubicin, in combination with dexrazoxane effective to ameliorate cardiotoxicity, classified in Class 424, subclass 130.1 .

Group 28 Claims 16, 19 is drawn to a kit/preparation comprising trastuzumab and dexrazoxane and a container, classified in Class 530, subclass 387.1 and Class 514, subclass 2+.

Group 29 Claims 17, 19 is drawn to a kit/preparation comprising trastuzumab, dexrazoxane, an anthacycline and a container classified in Class 530, subclass 387.1 and Class 514, subclass 2+.

Group 30 Claim 18 is drawn to a kit comprising trastuzumab, dexrazoxane, epirubicin and a container classified in Class 530, subclass 387.1 and Class 514, subclass 2+.

Group 31 Claims 20-22 are drawn to a dexrazoxane comprising trastuzumab, dexrazoxane, epirubicin and a container classified in Class 530, subclass 387.1 and Class 514, subclass 2+.

6. The inventions are distinct, each from the other because of the following reasons:

Inventions 1-27 are materially distinct methods which differ at least in objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success.

Inventions 28-31 as disclosed are biologically and chemically distinct, made by and used in different methods and are therefore distinct inventions.

The inventions of Groups 28/31 and 1-9 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (I) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see *MPEP* § **806.05(h)**]. In the instant case the drug products as claimed can be used in a materially different process such as an array for affinity chromatography.

The inventions of Groups 29/31 and 10-18 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (I) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see *MPEP* § **806.05(h)**]. In the instant case the drug products as claimed can be used in a materially different process such as an array for affinity chromatography.

The inventions of Groups 30/31 and 19-27 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (I) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see *MPEP* § **806.05(h)**]. In the instant case the drug products as claimed can be used in a materially different process such as an array for affinity chromatography.

The inventions of Groups 1-9 and 29/30 are not related because the methods of Groups 1-9 do not use all of the products of Groups 29/30.

The inventions of Groups 10-18 and 28/30 are not related because the methods of Groups 10-18 do not use all of the products of Groups 28/30.

The inventions of Groups 19-27 and 28/29 are not related because the methods of Groups 19-27 do not use all of the products of Groups 28/29.

7. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and/or

recognized divergent subject matter, restriction for examination purposes as indicated is proper.

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

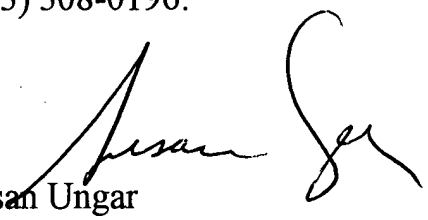
9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

10. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (571) 272-0837. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached at (571) 272-0871. The fax phone number for this Art Unit is (703) 305-7230.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Susan Ungar
Primary Patent Examiner
February 12, 2004